

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

PAMELA BUTLER,	)	
	)	
<i>Plaintiffs,</i>	)	Case No. 4:18-cv-01701-AGF
v.	)	
	)	Lead Case
MALLINCKRODT LLC, et al.	)	
	)	<b>ORAL ARGUMENT REQUESTED</b>
<i>Defendants.</i>	)	

**DEFENDANT MALLINCKRODT LLC’S REPLY IN SUPPORT OF ITS MOTION TO  
EXCLUDE THE TESTIMONY OF PLAINTIFFS’ EXPERT JAMES WELLS, PH.D**

Defendant Mallinckrodt LLC (“Mallinckrodt”) files this Reply in Support of its Motion to Exclude the Testimony of Plaintiffs’ Expert James Wells’ Ph.D. (Doc. #47.)

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## **I. INTRODUCTION**

Plaintiffs' opposition (Doc. #71) to Mallinckrodt's Motion to Exclude the Testimony of Plaintiff's Expert James Wells, Ph.D. employs several tactics to dodge the requirements of Rule 702 and the Court's gatekeeping function. Plaintiffs dismiss Dr. Wells' failure to properly apply the 10 C.F.R., Part 20 regulations by arguing the regulations do not apply to Mallinckrodt and are not appropriate for a Rule 702 motion. However, Dr. Wells relies on these regulations in his expert reports, and he opined Mallinckrodt violated them. Because he misapplied the standards central to his opinions, Mallinckrodt properly moved to exclude those opinions. Plaintiffs also ignore the fundamental failures in Dr. Wells' methodology and insufficient factual basis by falsely characterizing his deficiencies as "assumptions" or "disagreements." Even worse, they frequently misrepresent Dr. Wells' work to suggest he performed analyses he did not perform and attempt to manufacture new support—going so far as to submit new evidence while *omitting* the portions that refute the proposition for which Plaintiffs cite that evidence. These tactics accentuate the unreliability of Dr. Wells' work and the reason his opinions fail to meet the admissibility requirements of Rule 702. Plaintiffs have failed to carry their burden of establishing that Dr. Wells' testimony is the product of a reliable methodology, reliably applied to the facts in this case, and his testimony should be excluded pursuant to Rule 702.

## **II. STANDARD**

Signaling their lack of confidence in Dr. Wells' analysis and opinions, Plaintiffs argue the standard for admission of expert testimony is so minimal that it requires the admission of unscientific opinions, lacking factual support. Federal Rule of Evidence 702 and Eighth Circuit case law dispel this notion. Expert testimony can only be admitted if "based upon *sufficient* facts or data," "the product of *reliable principles and methods*," and "*the witness has applied the principles and methods reliably to the facts of the case.*" Fed. R. Evid. 702 (emphasis added).

Before admitting expert testimony, “the trial court must make ‘a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’” *Polski v. Quigley Corp.*, 538 F.3d 836, 838 (8th Cir. 2008) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993)). “Even a theory that might meet certain *Daubert* factors, such as peer review and publication, testing, known or potential error rate, and general acceptance, should not be admitted if it does not apply to the specific facts of the case.” *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000).

Plaintiffs attempt to dismiss the deficiencies in Dr. Wells’ methodology and factual basis by characterizing his unscientific approach as a factual “assumption” and Defendants’ challenge to his approach as a “disagreement” exempt from the Court’s scrutiny. (Doc. #71 at 7.) Plaintiffs’ invocation of *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007), is unavailing. *Hurst* was a trade secrets case, where plaintiff sued former employees for using confidential information to start their own venture. *Id.* at 953. Plaintiff sold probes that could be used with another manufacturer’s surgical lasers. *Id.* Defendants alleged plaintiff’s expert used an unreliable methodology for determining damages because the expert defined the relevant market of probe suppliers as two companies—plaintiff and defendant, without considering the laser manufacturer. *Id.* The expert explained the two-supplier market was used because he was quantifying the sales plaintiff lost to the defendants’ company, and this warranted only considering those two companies. *Id.* at 955. On these facts, the court found the methodology reliable with sufficient factual support for admission under Rule 702. *Id.* at 956. Contrary to Plaintiffs’ argument, the *Hurst* court did not hold a party can dodge Rule 702 and the Court’s gatekeeping function simply by calling the deficiencies in their expert’s testimony an “assumption” or a “disagreement.”

### **III. ARGUMENTS**

#### **A. Plaintiffs Fail to Meet Their Burden of Showing that Dr. Wells' Testimony Is Admissible Under Rule 702.**

The party offering an expert witness “must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid.” *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 589–90). This requires the proffering party to “show that the reasoning or methodology in question is applied properly to the facts in issue.” *Id.* at 758. “[O]pinion evidence that ‘is connected to existing data only by the *ipse dixit* of the expert’” must be excluded. *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). In weighing the *Daubert* factors, courts “must continue to function as a gatekeeper who ‘separates expert opinion evidence based on ‘good grounds’ from subjective speculation that masquerades as scientific knowledge.’” *Presley v. Lakewood Eng’g and Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (quoting *Glastetter v. Novartis Pharm Corp.*, 252 F3d 986, 989 (8th Cir. 2001)).

Mallinckrodt will address specific deficiencies in Dr. Wells’ opinions below, but, at a fundamental level, Plaintiffs’ opposition fails to show Dr. Wells used a scientifically valid methodology or apply that method reliably to the facts. Plaintiffs repeatedly assert in conclusory fashion that Dr. Wells used a reliable methodology. However, they fail to provide the Court with evidence showing his methodologies meet the *Daubert* factors or Rule 702. Plaintiffs fail to show whether Dr. Wells’ methodologies for determining the alleged releases of radioactive material have been tested, subject to peer review or publication, the potential error rate, or whether the methods have been generally accepted in the field of radiological science. *See Presley*, 643 F.3d at 643 (holding courts “determining the reliability of an expert’s opinion” should apply these *Daubert* factors). Merely stating that Dr. Wells’ opinions followed a reliable methodology cannot

meet their burden of showing reliability and compliance with Rule 702.

Further, many of Plaintiffs’ assertions are gross overstatements or outright falsehoods. For example, Plaintiffs attempt to legitimize Dr. Wells’ analysis by claiming “[h]e relie[d] on reference texts commonly accepted and held reliable by experts in the fields of environmental science, hydrogeology and contaminate fate and transport, as well as the generally-accepted principles and methodologies from those fields.” (Doc. #71 at 6.) But Plaintiffs never identify any of these “reference texts commonly accepted in the field.” While this boilerplate statement appears in Dr. Wells’ report, when asked about it in deposition, Dr. Wells admitted he cited no academic texts and was just referring to his general background knowledge. (Wells *Butler* 66:4–67:9, attached as **Exhibit Q**.)<sup>1</sup> Plaintiffs’ (and Dr. Wells’) failure to identify a single “reference text commonly accepted in the field” that supports his methodologies is fatal. Plaintiffs’ opposition also states, “Dr. Wells is able to calculate the past effluent concentrations in air, water, and sediment at the boundaries of these sites.” (Doc. #71 at 6.) However, other than a single thorium calculation from an air sample (discussed below), Dr. Wells admitted he did not and could not calculate release concentrations of radioactive materials from SLAPS. (Wells *Butler* 156:25–157:12; 158:25–159:20; 224:11–21.) Plaintiffs even claim that Dr. Wells “modeled” the alleged releases of thorium from SLAPS. (Doc. #71 at 8–9.) But Dr. Wells admitted he performed no such modeling for SLAPS. (Wells *Butler* 152:16–153:5.)

Plaintiffs’ opposition also illustrates Dr. Wells’ unscientific reliance on *ipse dixit*. In discussing his “allocation” opinion, Plaintiffs argue that Dr. Wells frequently uses the so-called

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<sup>1</sup> Mallinckrodt previously provided a copy of Dr. Wells’ deposition transcript for this matter as Doc. #48-4. For the Court’s convenience, Mallinckrodt is providing another copy of Dr. Wells’ deposition transcript. In the new copy, previously cited testimony is highlighted in yellow, and testimony cited in this reply brief is highlighted in blue.



Gore Factors in allocating clean-up responsibilities among defendants. (Doc. #71 at 12.) They also admit Dr. Wells could not calculate alleged exposures attributable to Mallinckrodt and Cotter. (Doc. #71 at 28.) Yet Mallinckrodt moved to exclude Dr. Wells' allocation opinions because he made up nonsensical numbers purportedly allocating fault between Mallinckrodt and Cotter, and relied on Gore Factors used in environmental cleanup allocation, not in tort litigation. (Doc. #48 at 18.) Plaintiffs never embrace their burden and explain how the numbers pass scientific muster. Instead, they simply say Dr. Wells is an expert and, therefore, his opinions are admissible. This *ipse dixit* fails to show how Dr. Wells' methodology is connected to the facts of this case and must be excluded. *See Marmo*, 457 F.3d at 758.

**B. Plaintiffs Fail to Meet Their Burden of Showing that Dr. Wells' Radon-222 Opinion Is Reliable.**

Mallinckrodt moved to exclude the testimony of Dr. Wells because he used an improper methodology, based on insufficient data, to opine that radon-222 was released from SLAPS from 1948 to 1966 in excess of the 1960 regulatory limit. (Doc. #48 at 9.) Dr. Wells' opinion was based solely on a 1948 measurement of radon conducted by the Atomic Energy Commission ("AEC"). (Doc. #48 at 9.) Moreover, the 1948 document he relied on identified "the source of [the radon] contamination [as] the K-65." (Doc. #48-7.) Critically, Plaintiffs do not dispute these facts. Even though the K-65 was removed by the end of 1949, and could no longer release radon from the site, Dr. Wells claimed the 1948 measurement alone was sufficient to determine radon releases from the site for the next 18 years. (Doc. #48 at 9–10.)

Neither Dr. Wells' reports nor Plaintiffs' opposition establish that he used a reliable methodology to support his radon opinion. As a starting point, Plaintiffs concede the 1948 measurement is Dr. Wells' *only* measurement data and do not dispute the AEC removed the K-65 material by the end of 1949. (Doc. #71 at 10, 22–24.) Unable to refute these facts, Plaintiffs claim

Dr. Wells “accounted for the removal of K-65” and argue the remaining radiological material released radon-222, albeit in an unspecified quantity. (Doc. #71 at 22.) Plaintiffs’ arguments, however, are inaccurate. Dr. Wells never “accounted” for the removal of the K-65. His expert report does not even mention the K-65, let alone its removal. (Doc. #48-1.) Further disproving Plaintiffs’ representation, Dr. Wells admitted he did not perform any calculations regarding the radon production. (Wells *Butler* 174:14–22.) He simply proclaimed the 1948 radon tests to be “broadly representative” of later releases, even though the conditions had irrefutably, substantially changed. (Doc. #48-1 at 17; Wells *Butler* 174:14–22.)

In their opposition, Plaintiffs attempt to invent new bases for Dr. Wells’ methodology that were not included in his original report or supplemental report. Plaintiffs contend the K-65 was a small portion of the total tonnage of residues at SLAPS. (Doc. #71 at 22). However, the pertinent issue is the concentration of radon-222 releases, not the relative tonnage of various materials. And Dr. Wells did not calculate any radon-222 releases or activity from these various other materials. (Wells *Butler* 177:4–8.) Notably, while Plaintiffs rely on Mallinckrodt’s experts’ determination of the tonnage of material, they ignore the same expert’s calculation of the release rate of radon-222. Table 4-38 in the same expert report—in the same section Plaintiffs cite—shows that the K-65 material provided over 95% of the radon-222 releases. (Doc. #48-13 at 122.) Simply put, nothing about the belated citation to relative tonnage sheds light on the fundamental failures associated with *Dr. Wells’* radon opinion.

Plaintiffs also argue the 1948 tests show radon concentrations from material other than the K-65. (Doc. #71 at 23.) Even if we ignore that this contention is not in Dr. Wells’ reports, the argument does not pass Rule 702 muster. The 1948 document expressly states: “A survey was made at the airport area in order to determine the concentrations of radon in air, *the source of this*

*contamination being the K-65* in and around the storage shed.” (Doc. #71-12 at 3) (emphasis added.) The report identifies no other material as a source of radon. Moreover, the measurements Plaintiffs reference were taken while the K-65 was on site, and there is no expert analysis distinguishing the K-65 contribution from the measured values. Thus, Plaintiffs’ attempt to belatedly assist Dr. Wells fails.

At bottom, Plaintiffs’ opposition confirms Dr. Wells’ radon-222 opinions are based solely on 1948 measurements taken to determine the release of radon *from the K-65 material*. Even though he knew this material was removed a year later, Dr. Wells failed to account for its removal or conduct any scientific analysis to determine post-removal radon releases. Ignoring this unfavorable data is the antithesis of scientific reliability, and it renders Dr. Wells’ radon-222 opinions fundamentally unsupported. As a result, they should be excluded.

**C. Plaintiffs Fail to Meet Their Burden of Showing that Dr. Wells’ Thorium-230 Opinion Is Reliable.**

Dr. Wells’ opinion that Mallinckrodt released thorium-230 in excess of 10 C.F.R. § 20.106 in 1960 is scientifically unreliable because he failed to average the measurements or use the limit for insoluble thorium. (Doc. #48 at 11.)

**1. Plaintiffs fail to meet their burden of showing Dr. Wells’ methodology for determining annual thorium releases in 1960 was reliable.**

Under 10 C.F.R. § 20.106 and case law construing the Price-Anderson Act, annual averages are required to determine compliance with the release limits. (Doc. #48 at 11–13.) The rationale is that the regulatory release limits correlate with annual dose limits. (Doc. #48-9 at 7.) Plaintiffs attempt to dodge this requirement and cure Dr. Wells’ flawed methodology by arguing the federal regulations do not apply because Mallinckrodt was not a licensee and the material was

waste product.<sup>2</sup> (Doc. #71 at 18.) However, they ignore that *Dr. Wells* used 10 C.F.R. § 20.106 in his analysis and claimed Mallinckrodt violated the regulation in 1960. (Doc. #48-1 at 28, Table 2.) Of course, Defendants here challenge the methodology of *Dr. Wells*' expert opinion, not alternative rationales proffered by the lay Plaintiffs that Dr. Wells himself did not follow.

Plaintiffs also present a strawman argument to the Court by misrepresenting Mallinckrodt's argument and the 1960 annual monitoring report Dr. Wells cited. Because Rule 702 requires an expert to reliably apply his methodology to the facts of the case, Mallinckrodt pointed out an erroneous factual assumption made by Dr. Wells: he incorrectly believed there were four measurements taken in 1960, when there were actually 12 measurements. (Doc. #48 at 11.) The 12 measurements were taken from four different locations: six tests from North of Site, 2 tests each from West, East, and South of the Site. (Doc. #48-10 at 11.) When Dr. Wells incorrectly wrote, "four samples were taken near the SLAPS property line," it is unclear if he did not understand that there were four sampling locations, and multiple tests, or thought only four tests were performed. (Doc. #48-1 at 19.) The text of his report would suggest it was the latter since he believed there was only a "day" of sampling in 1960. (Doc. #48-1 at 19.) Either way, the underlying facts are undisputed and Dr. Wells did not reliably apply those facts.

Plaintiffs also argue Mallinckrodt "asks the Court" to average tests from different locations, which is false. Plaintiffs misrepresent the 1960 annual report by claiming "it lists the 'average' of test results from *multiple* locations." (Doc. #71 at 21) (emphasis in original.) A review of the report, however, shows it lists the average for each location, but it never lists the average for multiple locations. (Doc. #48-10 at 11.) Indeed, Mallinckrodt never suggested averaging tests from different

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<sup>2</sup> As discussed in Section IV, the legal standards applicable to Mallinckrodt are not presently before the Court. The present issue is the admissibility of Dr. Wells' opinions under Rule 702, including his application of 10 C.F.R. Part 20.

locations. As set forth in the 1960 report, the appropriate averaging uses test results from the same location. (Doc. #48-10 at 11.) Mallinckrodt explained the average of the relevant tests was 60 percent less than the single, maximum number on which Dr. Wells exclusively relied. (Doc. #48 at 12.) The deposition testimony cited for this proposition states the average was 1.6, which the report shows as the average for the North of Site. (Wells *Butler* 195:23 to 196:7; Doc. #48-10 at 11.) As such, Dr. Wells had sufficient information to average the releases in 1960 for each location, but he simply chose to inflate the release value by using a single, maximum number.

Plaintiffs also attempt to justify Dr. Wells skewing the numbers by contending his use of the single, maximum number accounts for “high wind events.” (Doc. #71 at 13.) Neither Dr. Wells’ report nor Plaintiffs’ opposition provide any evidence that using a single, maximum value is a peer-reviewed or published methodology for accounting for wind. Plaintiffs do not provide evidence that this theory has been tested, and they do not address the potential error rate of such an approach. Moreover, other than Dr. Wells’ say-so, there is *no* evidence that Mallinckrodt did not collect air samples on windy days. As discussed above, Dr. Wells did not even know the number of tests performed or that there were multiple days of testing throughout the year. (Doc. #48-1 at 19.) Dr. Wells also provided no analysis of how wind would affect release rates. Plaintiffs repeatedly mention modeling, but Dr. Wells did not perform or use any modeling for SLAPS. (Wells *Butler* 152:16–153:2; 154:4–9.) Thus, Plaintiffs’ contention that Dr. Wells’ use of the single, maximum test result accounts for wind is simply an untested litigation-driven theory. *See Polksi v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008) (affirming exclusion of expert’s untested and unproven theory as unreliable).

**2. Plaintiffs fail to meet their burden of showing the reliability of Dr. Well’s methodology for concluding the thorium-230 at SLAPS was soluble.**

Like their argument regarding the averaging of releases, Plaintiffs’ argument that the

thorium-230 at SLAPS should be characterized as soluble is premised on demonstrably false assertions. As a threshold point, Dr. Wells did not analyze the solubility of the thorium-230 at SLAPS or reach a reasoned conclusion that it was soluble. He also admitted he did not research the solubility of environmental thorium in learned treatises. (Wells *Butler* 208:9–13.) Instead, he assumed it “should be classified as soluble” as a “precautionary principle” “in order to be conservative.” (Wells *Butler* 203:7–20.) In other words, he used the lower limit because it benefited his clients’ litigation strategy.

Plaintiffs now offer two arguments to create the illusion of scientific support for Dr. Wells’ baseless use of the soluble effluent limit. First, pointing to the 1979 Department of Energy Report (“DOE”), Plaintiffs claim the DOE “agrees” the thorium is “best defined as ‘soluble’ for purposes of regulation.” (Doc. #71 at 14.) Absent from their brief, however, is any citation to the DOE report or a quote where the DOE states this purported agreement. In contrast, Mallinckrodt provided the DOE report as an exhibit to its supporting brief. (Doc. #48-15.) The report clearly states the DOE provided the soluble release limit from 10 C.F.R. § 20.106 because it was the “[m]ore restrictive” value. (Doc. #48-15 at 66, Table 17.) Dr. Wells even acknowledged at his deposition that the DOE simply used the most restrictive number without performing any solubility testing. (Wells *Butler* 210:19–212:21.)

Second, Plaintiffs falsely represent that Cotter’s expert Malcolm R. Knapp, Ph.D. agrees that the thorium at issue was soluble and that the DOE report supports its solubility. (Doc. #71 at 25.) Plaintiffs supplied Dr. Knapp’s report, but *omitted* the part that explains he was “document[ing] the *erroneous manner* in which Dr. Wells estimated offsite releases and *compared them to the effluent concentration limits in Part 20.*” (Knapp Report at 31, attached as **Exhibit R**) (emphasis added). Under this section, Dr. Knapp states Dr. Wells should *not* have used the DOE

report for characterizing the thorium-230 as soluble. (Knapp Report at 32.) Referencing the DOE report, Dr. Knapp does state, “*if thorium dissolved in water* is to be compared to Part 20 limits, the appropriate limit is for soluble thorium.” (Knapp Report at 32.) But to determine if the thorium at issue dissolved in water, the Court need only reference table 1 in Dr. Wells’ report, where he cites the DOE water test results for thorium-230 as “ND,” which means not detected. (Doc. #71-1 at 27, Table 1; Wells *Butler* 276:12–277:4.) In other words, Dr. Wells’ own report provides reliable scientific evidence that the thorium-230 at SLAPS was *insoluble*, and Dr. Knapp’s report agrees.

Plaintiffs add yet another argument that is not found in Dr. Wells’ report or supplemental report: They claim a 1993 report from the Argonne National Laboratory lists thorium-230 values in water test results, so it must have dissolved in the water, meaning it was soluble. (Doc. #71 at 22.) Despite Plaintiffs claiming Dr. Wells reviewed “thousands of pages of documents,” his reports did not cite or rely on the Argonne report, he provided no analysis of this information, and thus he could not be questioned about in deposition. Nonetheless, the Argonne report undercuts Plaintiffs’ argument. Specifically, Table 2.5, cited by Plaintiffs, never says anything about the radionuclides being “dissolved in water.” (Doc. #71-13 at 72.) As such, any measured thorium-230 concentration would likely be from undissolved solids. More to the point, the Argonne report contains a section on the properties of various radionuclides, which Plaintiffs do not discuss. The section states: “*Most thorium compounds are insoluble*, bind to soils, and do not evaporate from soil or water into the air.” (Doc. #71-13 at 350 (emphasis added).) Accordingly, Plaintiffs’ argument—based on a report that Dr. Wells did not even cite—confirms the thorium-230 was insoluble.

Finally, Plaintiffs make several inaccurate statements about Mallinckrodt’s factual basis establishing the thorium was insoluble. For instance, they claim Mallinckrodt does not offer any expert evidence that the thorium-230 was insoluble. Not true. Mallinckrodt’s brief in support of

excluding Dr. Wells' testimony cited the reports of Risk Assessment Corporation ("RAC") and Dr. John Frazier establishing that use of the solubility limit for thorium-230 was wrong. (Doc. #48 at 14.) Next, they argue the report by Dick Duffey, Ph.D. from the University of Maryland is inadmissible. Federal Rule of Evidence 104(a) applies to rulings on the admissibility of expert evidence, and it does not require all underlying evidence to be admissible. *U.S. v. Martinez*, 3 F.3d 1191, 1196 n.10 (8th Cir. 1993). Additionally, Mallinckrodt obtained the Duffey report from the DOE, and RAC and Dr. Frazier both rely on it in forming their opinions pursuant to Rule 703. Accordingly, consideration of the Duffey report is appropriate, and, substantively, the Duffey report and ATSDR's *Toxicological Profile for Thorium* (Doc. #48-11), which Plaintiffs do not mention, establish that Dr. Wells' statement that the thorium was soluble is not only fundamentally unsupported, but wrong.

**D. Plaintiffs Fail to Meet Their Burden to Show Dr. Wells Is Qualified to Opine on Radiation Safety Standards.**

In addition to the scientific deficiencies in his work on this matter, Mallinckrodt moved to exclude Dr. Wells because he is not qualified to opine on radiation safety standards of care and regulations. (Doc. #48 at 20–21.) Experts must possess knowledge and skill related to the specific subject matter of their proffered testimony. When an expert strays beyond their expertise, they must be excluded. *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 723 (8th Cir. 2015). As recognized in the *Robinson v. Geico General Ins. Co.* case cited by Plaintiffs, "Rule 702 does require that 'the area of *the witness's competence matches the subject matter of the witness's testimony.*'" 447 F.3d 1096, 1101 (8th Cir. 2006) (emphasis added).

Despite citing *Robinson*, Plaintiffs only discuss Dr. Wells' qualifications in general terms; they never show that his proclaimed expertise matches the subject matter of his testimony. They repeatedly tout his education and work as an environmental geologist (Doc. #71 at 8), but the



subject matter of this case is radiation, not geology. They discuss his work on the editorial board of an environmental forensics journal, but they never describe any publications he has authored or peer reviewed related to radioactive material. That is because, as Dr. Wells conceded at his deposition, he has never published on radioactive waste or radionuclides. (Wells *Butler* 32:8–10.) Not only do Plaintiffs fail to show how Dr. Wells’ expertise relates to his work in this case, they discuss all his qualifications and expertise without even using the word radiation.

Plaintiffs’ discussion of Dr. Wells’ inapplicable experience and background does not refute Mallinckrodt’s assessment of his qualifications. Plaintiffs do not dispute that he did not complete any coursework in radiation, health physics, or radiation safety. (Doc. #48 at 21.) They do not dispute that Dr. Wells is not a member of any professional societies related to radiation or radiation safety. They do not dispute that he has never worked in a facility with a radioactive material license or similar facility. Critically, they also fail to dispute—because they cannot—that Dr. Wells is not an expert in the AEC regulations, and this case is the one and only time that he has ever analyzed compliance with the AEC regulations or any federal radiation safety standard. (Doc. #48 at 22.) These are not mere gaps in Dr. Wells’ knowledge and expertise. Dr. Wells is acting wholly outside of his area of expertise as a geologist, and his testimony should be excluded.

#### **IV. QUESTIONS OF LAW**

Plaintiffs devote a considerable portion of their brief to arguing issues related to the legal standard applicable to Mallinckrodt’s activities, including alleging Mallinckrodt should be subject to strict liability. For support, Plaintiffs cite to the Court’s February 27, 2015 ruling on an earlier motion to dismiss. (Doc. #71 at 117; Doc. #262.)<sup>3</sup> However, in ruling on the motion to dismiss over six years ago, the Court had to accept all of Plaintiffs’ allegations as true. *Braden v. Wal-Mart*

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<sup>3</sup> Document No. 262 was issued in Case No. 4:12-cv-00361-AGF.

*Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009). This included the inaccurate allegations that all of Mallinckrodt's activities occurred before 1957 and were not subject to any federal radiation safety standards. (Doc. #262 at 2–4.) Mallinckrodt disputes Plaintiffs' assertions, and the applicability of certain regulations and standards of care are addressed in Mallinckrodt's expert's reports (*see* Doc. #48-14 at 3, 9–31) and will be the subject of future motion practice, including dispositive motions. However, those legal theories and standards are not presently before the Court or the subject of Mallinckrodt's motion to exclude the testimony of Dr. Wells.

Mallinckrodt's motion to exclude the opinions of Dr. Wells appropriately challenges the opinions rendered in his reports. (Doc. #48.) Moreover, Plaintiffs cannot dispute that Dr. Wells' expert reports claim to apply the 10 C.F.R., Part 20 regulations to Mallinckrodt's activities. (Doc. #48-1 at 14–17, 19, 22, 27–28; Doc. #48-5 at 11.) Dr. Wells even opines Mallinckrodt violated the 10 C.F.R., Part 20 regulations by releasing radon and thorium-230 above the regulatory limits. (Doc. #48-1 at 17, 19, 22, 28; Doc. #48-5 at 11.) As such, the admissibility of his opinions, including applying the regulations he claims to apply, is properly the subject of a Rule 702 motion.

## **V. CONCLUSION**

For the reasons stated above and more fully in Mallinckrodt's Motion and Memorandum in Support of Its Motion to Exclude the Testimony of Plaintiffs' Expert James Wells, Ph.D., Mallinckrodt respectfully requests this Court to enter an Order excluding the testimony and opinions of plaintiffs' expert James Wells.

Dated: October 22, 2021

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 22nd day of October, 2021, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ David R. Erickson